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Pesticide Assessment Guidelines Subdivision F, Hazard Evaluation: Human and Domestic Animals. Dermal Sensitization Addendum 4 on Data Reporting

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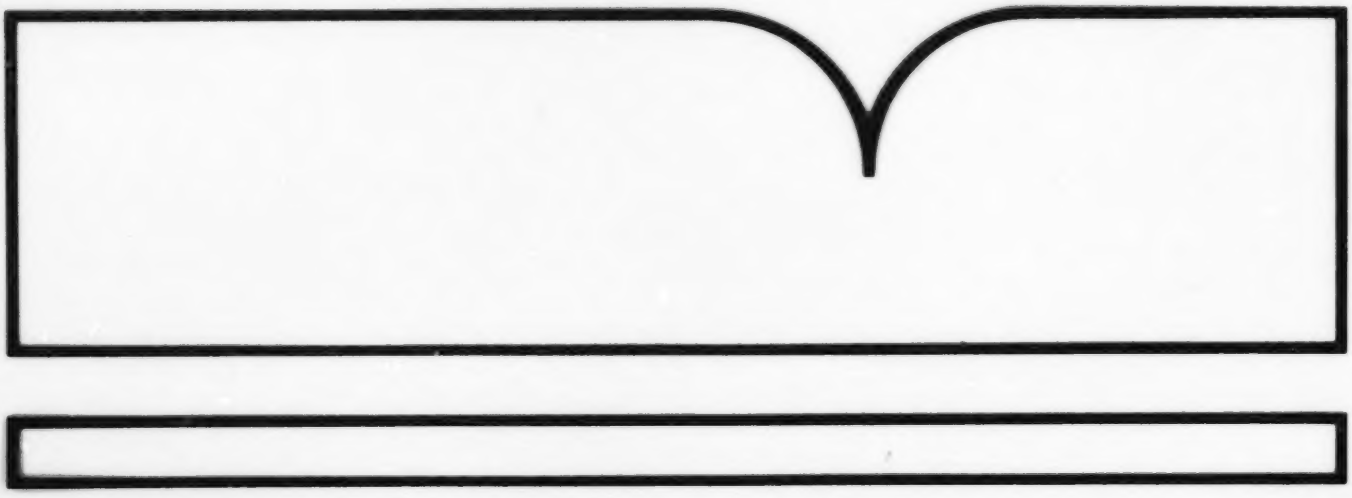

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Addendum 4 to Pesticide Assessment Guidelines, Subdivision F, Hazard Evaluation: Human and Domestic Animals (EPA 540/9-82-025 and NTIS Order Number PB83-153916), October, 1982

16. Abstract (Limit: 200 words)
The Data Reporting Guideline (DRG) for Dermal Sensitization, Series 81-6, gives guidance to pesticide registrants on the format of their study report so that the Agency can review it efficiently. This guidance clarifies sections in the existing Pesticide Assessment Guidelines, Subdivision F, on data reporting and applies to any of the seven acceptable tests. It provides an outline for the study report which data submitters can use in preparing their reports for submission to EPA to meet 40 CFR 158 data requirements for the registration of pesticides.

The DRG for Series 81-6, Dermal Sensitization, is only one of a number of DRGs published by the National Technical Information Service as an addendum to Subdivision F of the Pesticide Assessment Guidelines.

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PESTICIDE ASSESSMENT GUIDELINES

SUBDIVISION F

HAZARD EVALUATION:

HUMAN AND DOMESTIC ANIMALS

Series 81-6

Dermal Sensitization

ADDENDUM 4 ON DATA REPORTING

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Subdivision F - Dermal Sensitization

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PESTICIDE ASSESSMENT GUIDELINES

HUMAN AND DOMESTIC ANIMALS

Dermal Sensitization

Subdivision F, Series 81-6

DATA REPORTING

INTRODUCTION

A. Purpose

The purpose of this guideline is to provide a reporting format for dermal sensitization studies.

B. Objective

This guideline is designed to aid the registrant in the preparation and submission of reports which are compatable with the Agency's review process. Following the guideline is not mandatory except to the extent for compliance with PR Notice 86-5, but registrants are encouraged to submit reports in this format.

RESPONSE TO PUBLIC COMMENTS

The Agency received one response on dermal sensitization studies to its request for public comments published in the FEDERAL REGISTER of March 25, 1987 (52 FR 9536). The general comments concerning purpose, objective, guideline, and summary were taken under advisement, and changes were made to better conform to the PR Notice 86-5. Comments on changes in the appendices were considered but not adopted.

GUIDELINE

The Final Report should contain the following items.

COVER PAGE

The title page and additonal documentation (i.e., requirements for data submission, Good Laboratory Practices statement, and statement of data confidentiality claims), if relevant to the study report, must precede the content of the study format below. These requirements are described in PR Notice 86-5.

TABLE OF CONTENTS

This item should be a concise listing of the essential elements of the Final Report including the page numbers for each. Essential elements should include the following: Summary, Introduction, Materials and Methods, Results, Discussion, Bibliography, Tables, Figures, Appendices, and key subsections as appropriate.

BODY OF REPORT

This item shall include all information required in §80-4(b)(2), §80-4(c), and §81-6. Additional recommendations are provided in paragraphs identified as III and IV of this addendum.

I. SUMMARY

As per §80-4(b)(1) of this Subdivision, this section of the test report shall contain a summary and analysis of the data and a statement of the conclusions drawn from the analysis. This summary should highlight any and all positive data or observations and any deviations from control data which may be indicative of toxic effects.

II. INTRODUCTION (include the objectives of the study).

III. MATERIALS/METHODS

This section of the Final Report shall include information required by §80-4 of this Subdivision, and it may also contain the following descriptions specific to dermal sensitization.

A. See §81-5 and the Standard Evaluation Procedure (SEP)[1/] for details.

B. Since any one of seven tests are acceptable, we do not provide examples of data formats. In general, follow §81-5 and §80-4 in addition to the other requirements [49 FR (188) 37596 (9/26/84)]. §81.5: "...the test report shall include the following information: A description of the method used and the commonly accepted name; information on positive control study, including positive control used, method used, and time conducted; the number, species, strain and sex of the test animals; individual weights of the animals at the start of the test and at the conclusion of the test; a brief description of the grading system; and each reading made on each individual animal."

IV. RESULTS

Summary Tables. Paragraph 81-6 and §80-4 require results to be summarized in tabular form.

V. DISCUSSION

VI. BIBLIOGRAPHY

VII. VERIFICATION

This item shall contain information required by §80-4(b)(2). Each test report shall be:

1/ The SEP for Dermal Sensitization is to be published. It aids Agency reviewers in the evaluation of a report submitted in the registration of a pesticide.

A. Signed by each of the senior scientific personnel, including the laboratory director responsible for performing and supervising the testing, preparing, reviewing, and approval of the test report.

B. Certified by the applicant or an authorized agent of the applicant as a complete and unaltered copy of the report provided by the testing laboratory whether independent or owned, operated, or controlled by the applicant.

VIII. ARCHIVES

This section of the Final Report shall contain all information required in 40 CFR Part 160.185.

IX. TABLES/FIGURES

X. APPENDIX(ES)

These should include individual animal data, histopathology (if indicated), source of animals, diet, animal weights, protocol, and other information as appropriate.